Doc code: IDS Doc description: Information Disclosure Statement (IDS) Filed

PTO/SB/08a (07-09)
Approved for use through 07/31/2012. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

| | Application Number | | 10597963 |
|---|----------------------|--------|----------------|
| INFORMATION BIOOLOGUEE | Filing Date | | 2006-08-15 |
| INFORMATION DISCLOSURE | First Named Inventor | Veron | esi |
| STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99) | Art Unit | | 1611 |
| (Not for Submission under or or K 1.00) | Examiner Name | Charle | esworth E. Rae |
| | Attorney Docket Numb | er | IPU1954-009 |

| | | | | U.S. | PATENTS | |
|----------------------|------------|---------------|---------------------------|------------|---|--|
| Examiner Initial* | Cite No | Patent Number | Kind Code ¹ | Issue Date | Name of Patentee or Applicant of cited Document | Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear |
| | 1 | 3931141 | | 1976-01-06 | Wissmann et al. | |
| | 2 | 4001327 | | 1977-01-05 | Lucchesi | |
| | 3 | 4236509 | | 1980-12-02 | Takahashi et al. | |
| | 4 | 4368193 | | 1983-01-11 | Argoudelis et al. | |
| | 5 | 4423067 | | 1983-12-27 | Skuballa et al. | |
| | 6 | 4464466 | | 1984-08-07 | Argoudelis et al. | |
| | 7 | 4613500 | | 1986-09-23 | Suzuki et al. | |
| | 8 | 4832954 | | 1989-05-23 | Sato et al. | |

| | | · |
|------------------------|-------|----------------|
| Application Number | | 10597963 |
| Filing Date | | 2006-08-15 |
| First Named Inventor | Veron | esi |
| Art Unit | | 1611 |
| Examiner Name Charle | | esworth E. Rae |
| Attorney Docket Number | | IPU1954-009 |

| 9 | 5057317 | | 1991-10-15 | lida | |
|----|---------|--------|------------|------------------|--|
| 10 | | | 1991-10-22 | Yamamoto et al. | |
| 11 | 5080906 | | 1992-01-14 | Carenzi et al. | |
| 12 | 5112604 | | 1992-05-12 | Beaurline et al. | |
| 13 | 5188840 | | 1993-02-23 | lida et al. | |
| 14 | 5580576 | | 1996-12-03 | Veronesi et al. | |
| 15 | 5582591 | | 1996-12-10 | Cheikh | |
| 16 | 5733569 | | 1998-03-31 | Azria et al. | |
| 17 | 5759565 | | 1998-06-02 | Azria et al. | |
| 18 | 5776885 | 111,11 | 1998-07-07 | Orsolini et al. | |
| 19 | 6333044 | B1 | 2001-12-25 | Santus et al. | |

| Application Number | | 10597963 |
|------------------------|-------|----------------|
| Filing Date | _ | 2006-08-15 |
| First Named Inventor | Veron | esi |
| Art Unit | | 1611 |
| Examiner Name Charle | | esworth E. Rae |
| Attorney Docket Number | | IPU1954-009 |

| 20 | 6376461 | B1 | 2002-04-23 | Igari et al. | |
|----|-----------|----|------------|--------------------|--|
| 2 | 6440392 | B1 | 2002-08-27 | Stern | |
| 22 | 2 6500808 | B2 | 2002-12-31 | Killam | |
| 23 | 6577947 | B1 | 2003-06-10 | Kronfeld et al. | |
| 24 | 4 6623732 | B1 | 2003-09-23 | Ма | |
| 25 | 6638915 | B1 | 2003-10-28 | Killam | |
| 26 | 6734162 | B2 | 2004-05-11 | Van Antwerp et al. | |
| 2 | 7 7022687 | B1 | 2006-04-04 | Szelenyl et al. | |
| 28 | 3 7045323 | B2 | 2006-05-16 | Ansovini | |
| 29 | 7348360 | B2 | 2008-03-25 | Hensley et al. | |
| 30 | 7572599 | B2 | 2009-08-11 | Lee et al. | |

| Application Number | | 10597963 |
|------------------------|--------|----------------|
| Filing Date | | 2006-08-15 |
| First Named Inventor | Veron | nesi |
| Art Unit | | 1611 |
| Examiner Name | Charle | esworth E. Rae |
| Attorney Docket Number | | IPU1954-009 |

| | | | U.S.P | ATENT APPL | ICATION PUBLICATIONS | |
|----------------------|--------------------|-------------------------------|---------------------------|-----------------------|---|--|
| Examiner Initial* | Cite N o | Publication Number | Kind Code ¹ | Publication Date | Name of Patentee or Applicant of cited Document | Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear |
| | 1 | 20040033260 | A1 | 2004-02-19 | Rennie et al. | |
| | 2 | 20040138118 | A1 | 2004-07-15 | Wolfman et al. | |
| | 3 | 20040224890 | A1 | 2004-11-11 | Quay et al. | |
| | 4 | 20050158247 | A1 | 2005-07-21 | Veronesi et al. | |
| | 5 | 20060275280 | A1 | 2006-12-07 | Lee et al. | |
| | 6 | 20070265337 | A1 | 2007-11-15 | Hensley et al. | |
| | 7 | 20080085298 | A1 | 2008-04-10 | Pohl et al. | |
| | 8 | 20090035260 | A1 | 2009-02-05 | Veronesi et al. | |
| l If you wish | n to ac | l dd additional U.S. Publi | shed Ap | I plication citati | _I on information please click the Ad | l d button. |

| Application Number | | 10597963 |
|------------------------|-------|----------------|
| Filing Date | | 2006-08-15 |
| First Named Inventor | Veron | esi |
| Art Unit | | 1611 |
| Examiner Name | Charl | esworth E. Rae |
| Attorney Docket Number | | IPU1954-009 |

| Examiner Initial* | Cite No | Foreign Document Number ³ | Country Code ² i | Kind Code ⁴ | Publication Date | Name of Patentee or Applicant of cited Document | Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear | T5 | | | |
|-----------------------|------------|--|--------------------------------|---------------------------|---------------------|--|--|------------|--|--|--|
| | 1 | 0094157 | EP | A1 | 1983-11-16 | Takeda Chemical Industries, Ltd. | | | | | |
| | 2 | 0468182 | EP | A1 | 1992-01-29 | Sclavo S.p.A. | | | | | |
| | 3 | 1539318 | GB | -11 - 3 | 1979-01-31 | Ferring AB | | | | | |
| | 4 | 01243742 | IT | В | 1994-06-21 | Istituto Biochimico Nazionale Savio S.r.l. | In Italian, English abstract attached | × | | | |
| | 5 | 55-55120 | JP | A | 1980-04-22 | Sandoz AG | In Japanese, English abstract attached | | | | |
| | 6 | 55-66517 | JP | А | 1980-05-20 | Sandoz AG | In Japanese, relevance discussed in paragraph [009] of the written specification | | | | |
| | 7 | 2007/126865 | wo | A2 | 2007-11-08 | Patrin Pharma | | | | | |
| If you wish | n to ac | l dd additional Foreign I | | | • | l please click the Add butto | on | | | | |
| | | Г | NON-PA | TENT LITE | RATURE DO | CUMENTS | 1 | | | | |
| Examiner Initials* | Cite No | | ırnal, serial, sy | mposium, | catalog, etc), | the article (when appropertion of the article (when appropertion of the article (when appropertion) the article (when appropertion) and the article (when appropertion) are th | | T 5 | | | |
| | 1 | BERGQUIST, C. ET AL., Intranasal Gonadotropin-Releasing Hormone Agonist As A Contraceptive Agent, The Lancet, August 4, 1979, pp. 215-216, 11(8136), Boston, Massachusetts and London. | | | | | | | | | |

| Application Number | | 10597963 |
|------------------------|-------|----------------|
| Filing Date | | 2006-08-15 |
| First Named Inventor | Veror | nesi |
| Art Unit | | 1611 |
| Examiner Name | Charl | esworth E. Rae |
| Attorney Docket Number | | IPU1954-009 |

| 2 | BRUYNZEEL, D.P. ET AL., Contact dermatitis to lauryl pyridinium chloride and benzoxonium chloride, Contact Dermatitis, Short Communications, 1987, pp. 41-42, 17, Blackwell Munksgaard, Copenhagen, Denmark. | |
|----|---|--|
| 3 | BUDAVARI, S. ET AL., The Merck Index, 1996, pp. 2146, Twelfth Edition, Merck & Co., Inc., Whitehouse Station, New Jersey. | |
| 4 | CHEVANCE, L.G. ET AL., Etude Des Rythmes Du Battement Ciliaire, Acta Oto-Laryngologica, July 1970, pp. 16-28, 70(1), Taylor & Francis AB, Stockholm, Sweden. | |
| 5 | DUA, R. ET AL., The influence of tonicity and viscosity on the intranasal absorption of salmon calcitonin in rabbits, International Journal Of Pharmaceutics, 1997, pp. 233-242, 147, Elsevier BV, Amsterdam, Netherlands. | |
| 6 | EL-SAYED, G.M., The role of tromethamine as a dissolution and bioavailability enhancer of oral glibenclamide, STP Pharma Sciences, 1998, pp. 169-173, 8(3), Editions de sante, Paris, France. | |
| 7 | FELBER, J.P. ET AL., Administration by Nasal Spray of an 18 Amino Acid Synthetic Polypeptide with Corticotropic Action, Experientia, November 15, 1969, pp. 1195-1196, 25(11). | |
| 8 | FISHER, A.A., Allergic Contact Dermatitis and Conjunctivitis from Benzalkonium Chloride, Cutis, May 1987, pp. 381-383, 39, Quadrant HealthCom, Chatham, New Jersey. | |
| 9 | GENNSER, G. ET AL., Intranasal Administration of Luteinising-Hormone Releasing Factor, The Lancet, May 4, 1974, pp. 865-866, 1(7862), Boston, Massachusetts and London. | |
| 10 | GREENBERG, S.B. ET AL., Antiviral Activity of Intranasally Applied Human Leukocyte Interferon, Antimicrobial Agents and Chemotherapy, October 1978, pp. 596-600, 14(4), American Society for Microbiology, Washington, D.C. | |
| 11 | JAPAN DIABETES SOCIETY, Summary, 1974, pp. 237 and 253, 17, Journal of the Diabetic Society, Tokyo, Japan. | |
| 12 | LEMP, M.A. ET AL., Toxic Endothelial Degeneration in Ocular Surface Disease Treated With Topical Medications Containing Benzalkonium Chloride, American Journal of Ophthalmology, June 1988, pp. 670-673, 105(6), Elsevier Inc, New York, New York. | |

| Application Number | | 10597963 | |
|------------------------|---------------------|-------------|--|
| Filing Date | | 2006-08-15 | |
| First Named Inventor | Veronesi | | |
| Art Unit | | 1611 | |
| Examiner Name | Charlesworth E. Rae | | |
| Attorney Docket Number | | IPU1954-009 | |

| | r | r | | | 1 | | | |
|-------------------------------------|--------------------------------|--|--|-----------------------------|--------|--|--|--|
| | 13 | MOREN, F. ET AL., Aerosols in Medicine, Principles, Diagnosis and Therapy, 1993, pp. 346, Second, revised edition, Elsevier Science Publishers B.V., Amsterdam, Netherlands. | | | | | | |
| | 14 | NISHIHATA, T. ET AL., Enhanced rectal absorption of insulin and heparin in rats in the presence of non-surfactant adjuvants, Journal of Pharmacy and Pharmacology, Communications, 1981, pp. 334-335, Pharmaceutical Press, London, United Kingdom. | | | | | | |
| | 15 | PONTIROLI, A.E. ET AL., Insulin given intranasally induces hypoglycaemia in normal and diabetic subjects, British Medical Journal, Papers and Short Reports, January 30, 1982, pp. 303-306, 284, BMJ Publishing Group, London, United Kingdom. | | | | | | |
| | 16 | THE EUROPEAN AGENCY FOR THE EVALUATION OF MEDICINAL PRODUCTS, Committee For Proprietary Medicinal Products, Note For Guidance On In-Use Stability Testing Of Human Medicinal Products, March 1, 2001, 3 pages, CPMP/QWP/2934/99, London, United Kingdom. | | | | | | |
| | 17 | WIGLEY, F.M. ET AL., Insulin Across Respiratory Mucosae by Aerosol Delivery, Diabetes, August 1971, pp. 552-556, 20(8), American Diabetes Association, Alexandria, Virginia. | | | | | | |
| If you wis | h to a | dd add | litional non-patent literature document citation information please click the Add b | utton | | | | |
| | | | EXAMINER SIGNATURE | | | | | |
| Examiner Signature | | ture | Date Considered | | | | | |
| | | | reference considered, whether or not citation is in conformance with MPEP 609. rmance and not considered. Include copy of this form with next communication t | • | | | | |
| Standard S ⁻⁴ Kind of do | T.3). ³ F cument | or Japa by the a | O Patent Documents at www.uspto.gov or MPEP 901.04. ² Enter office that issued the documer anese patent documents, the indication of the year of the reign of the Emperor must precede the seri appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. ⁵ Application is attached. | al number of the patent doc | ument. | | | |